IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Demopoulos, H. et al.

Serial No.: Not Yet Assigned

Filed :

For : PHARMACEUTICAL PREPARATIONS OF GLUTATHIONE AND METHODS OF ADMINISTRATION THEREOF

February 25, 2002

Hon. Commissioner of Patents
and Trademarks
Washington, DC 20231

Sir:

PRELIMINARY AMENDMENT

Prior to examination on the merits, please amend the application as follows:

IN THE SPECIFICATION:

Page 1, line 1, before first paragraph, insert the following paragraph:

--The present application claims benefit of priority from Provisional Patent Application No. 60/034,101, filed December 31, 1996, and claims benefit of priority under 35 U.S.C. § 371 from PCT/US/23879, and is a continuation of U.S. Patent Application No. 09/331,947, to be issued as U.S. Patent No. 6,350,467 on February 26, 2002, each of which is expressly incorporated herein by reference. This application is related to U.S. Patent Application Serial No. 09/002,100, now U.S. Pat. No. 6,159,500, U.S. Patent Application Serial No. 09/457,642, now U.S. Pat. No. 6,204,248, and U.S. Patent Application No. 09/813,247 (allowed).--

IN THE CLAIMS

Please cancel claims 1-59.

Please add new claims 60-79 as follows:

60. An pharmaceutical formulation in oral unit dosage form, comprising Glutathione, said formulation being in such form adapted to modify vascular tone in an organism administered said formulation.

61. The formulation according to claim 1, wherein the formulation acts as a vasodilator through alteration of nitric oxide metabolism.

62. The formulation method according to claim 1, wherein the formulation is effective for treating pathological vasospasm.

63. The method according to claim 1, wherein the formulation is effective for treating sexual dysfunction.

64. The formulation according to claim 1, in combination with a drug effective to treat congestive heart failure.

65. The formulation according to claim 1, further comprising a physiologic nitric oxide precursor.

66. The formulation according to claim 6, wherein the nitric oxide precursor is arginine.

67. The formulation according to claim 6, wherein said formulation comprises about 500 mg reduced L-glutathione, about 200 mg ascorbic acid, and about 200 mg arginine.

68. The formulation according to claim 6, wherein the nitric oxide precursor comprises a pharmaceutically acceptable vasodilator.

69. The formulation according to claim 6, wherein the nitric oxide precursor comprises an NO_2 functionality.

70. The formulation according to claim 10, wherein the nitric oxide precursor comprises an organic nitrate.

71. The formulation according to claim 1, further comprising an antibiotic agent.

72. A pharmaceutical composition in oral unit dosage form, comprising in combination glutathione and an antiviral or antimicrobial antibiotic agent.

73. The pharmaceutical composition according to claim 13, wherein said antibiotic agent comprises an antibiotic having activity against mycoplasma infection.

74. The pharmaceutical composition according to claim 13, wherein said antibiotic agent comprises an antibiotic having activity against viral infection.

75. The pharmaceutical composition according to claim 13, wherein said antimicrobial agent comprises an antibiotic in sufficient amount to suppress growth of a microbe and said glutathione is provided in sufficient amount to control free radical reactions associated with the microbe.

76. The pharmaceutical composition according to claim 13, wherein said composition is provided in an oral dosage form

77. The pharmaceutical composition according to claim 13, wherein said antibiotic agent comprises an aminoglycoside.

78. The pharmaceutical composition according to claim 13, wherein said antibiotic agent comprises a quinolone antibiotic.

79. The pharmaceutical composition according to claim 13, wherein said formulation is adapted to modify vascular tone in an organism administered said formulation.

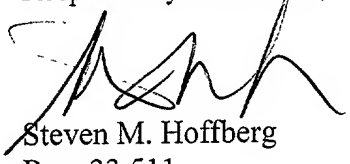
REMARKS

Claims 60-79 are in the application. Claims 1-59 are cancelled herein by preliminary amendment.

The Examiner is respectfully requested to review the related patents and patent applications, including references cited therein.

Applicants provide herewith a set of PTO-1449 (substitute) listing the references cited in these related applications. An additional PTO-1449 is provided for newly cited reference. The Examiner is respectfully requested to initial the forms and return a copy to applicants' undersigned attorney.

Respectfully Submitted,



Steven M. Hoffberg
Reg. 33,511

February 25, 2002

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CLEAN COPY OF AMENDED SPECIFICATION

PAGE 1, LINE 1

The present application claims benefit of priority from Provisional Patent Application No. 60/034,101, filed December 31, 1996, and claims benefit of priority under 35 U.S.C. § 371 from PCT/US/23879, and is a continuation of U.S. Patent Application No. 09/331,947, to be issued as U.S. Patent No. 6,350,467 on February 26, 2002, each of which is expressly incorporated herein by reference. This application is related to U.S. Patent Application Serial No. 09/002,100, now U.S. Pat. No. 6,159,500, U.S. Patent Application Serial No. 09/457,642, now U.S. Pat. No. 6,204,248, and U.S. Patent Application No. 09/813,247 (allowed).

CLEAN COPY OF NEWLY ADDED CLAIMS

60. An pharmaceutical formulation in oral unit dosage form, comprising Glutathione, said formulation being in such form adapted to modify vascular tone in an organism administered said formulation.

61. The formulation according to claim 1, wherein the formulation acts as a vasodilator through alteration of nitric oxide metabolism.

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Applicant(s)	:	Demopoulos, et al.
Serial No.	:	Continuation of 09/331,947
Filed	:	6/28/99
For	:	PHARMACEUTICAL PREPARATIONS OF GLUTATHIONE AND METHODS OF ADMINISTRATION THEREOF
Art Unit	:	1615
Examiner	:	J. Spear

February 25, 2002

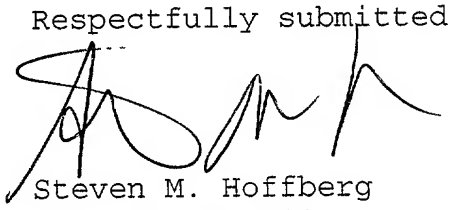
Hon. Commissioner of Patents
& Trademarks
Washington, DC 20231

Sir:

LETTER TO THE OFFICIAL DRAFTSMAN

Enclosed herewith are two sheets of formal drawings for the above referenced patent application. Approval of the formal aspects thereof is respectfully solicited.

Respectfully submitted,



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2 grams/day

GSH in PBMCs, Patient G

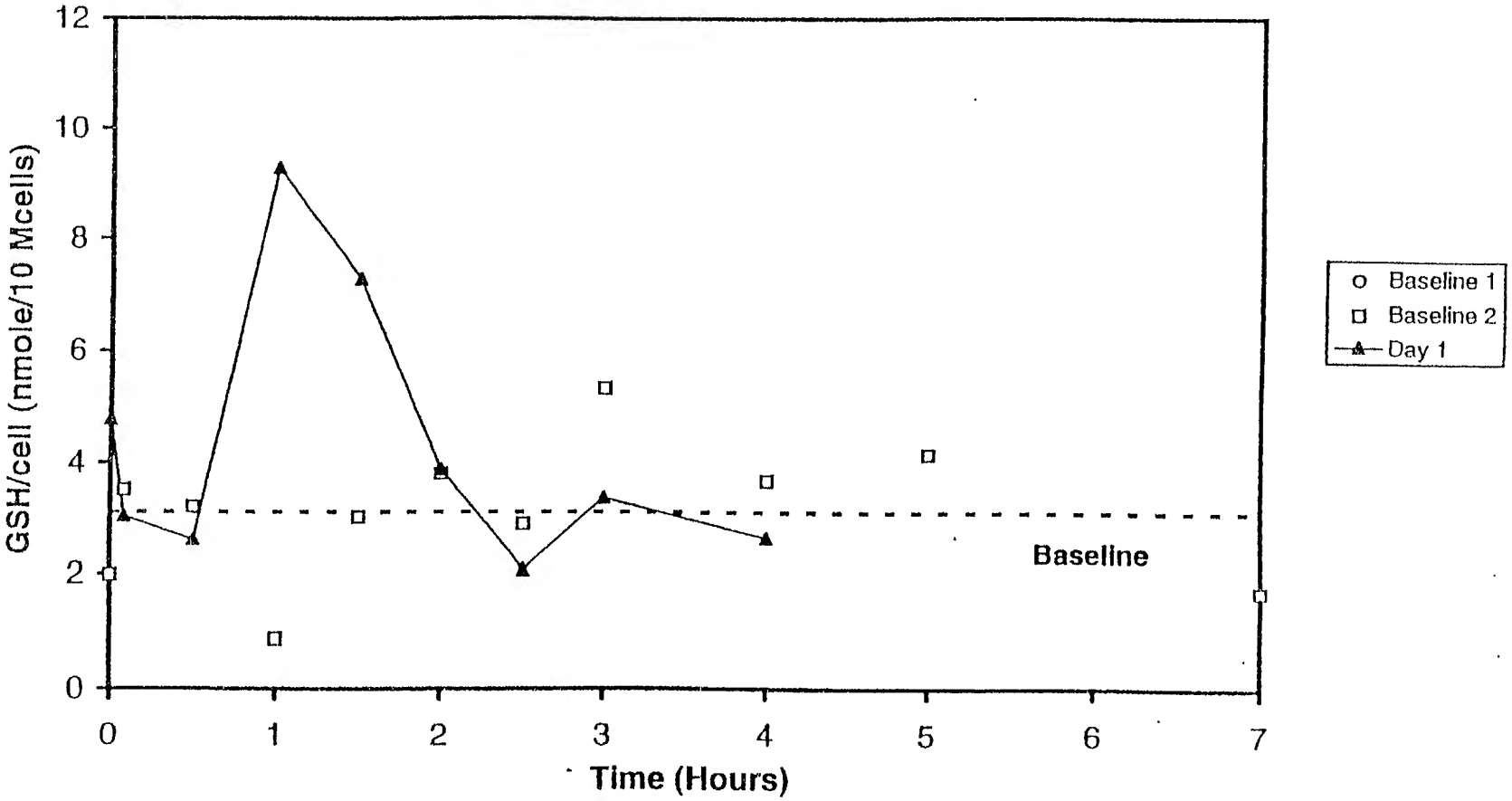

Fig. 1

Thyone™-500, Given Orally, Markedly Raises Glutathione Levels Inside the Immune Cells of HIV Positive People.

Dosage Regimen	Responders	Percent Increases
3 grams/day 1.5 Grams, 2x/day	100% 6 out of 6 people Average Ranges:	 53% - 99%
2 grams/day 1.0 grams, 2x/day	75% 6 out of 8 people Average Ranges:	 42% - 87%
1 gram/day 0.5 grams, 2x/day	40% 2 out of 5 people Average Ranges:	 8% - 60%

These results show a dose-response effect in that 3 grams/day result in positive responses, in more people, and the responses are greater...compared to 2 grams/day, and 1 gram/day.

Fig. 2